

**REMARKS**

Claim 1 has been amended, claims 10-22 and 27-38 have been cancelled by this amendment.

No new subject matter has been added by this amendment.

Claims 1-9, and 23-26 are now currently pending in this application.

**Claim Objection**

Claim 1 was objected to because of the following informality recited by the Examiner:

In regards to claim 1, at line 7, insert --being-- between "collar" and "received."

Applicants have amended claim 1 as provided by the Examiner and believe this objection has been overcome.

**Claims Rejections – 35 USC § 102**

(A) Claims 1-6, 9-10, 13-14, 17-20, 22, 27, and 30-38 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,982,842 to Hollister ("Hollister").

This rejection is respectfully traversed with respect to the amendment to claim 1.

Of the claims rejected, claims 10, 13, 14, 17-20, 22, 27, 30-38 have been cancelled, amended claim 1 is independent, with the remaining claims dependent thereon.

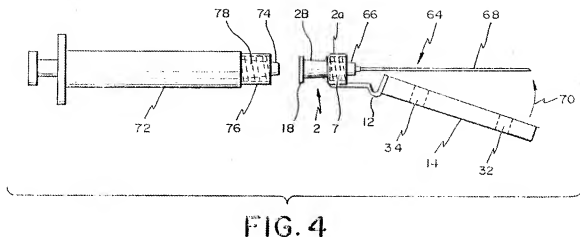
Claim 1 now recites, among other things:

*a holder housing adapted to receive a sample collection tube within a rearward end,.....*

*wherein the safety shield and the collar are rotatable with respect to the holder housing about an axis of the holder housing, such that the safety shield and the collar can be radially rotated to a desired position around the axis without the axial movement of the collar along the axis.*

Applicants submit that Hollister fails to disclose at least the claimed features of: (a) a collar and a shield that can be radially rotated with respect to a holder housing about an axis of the holder housing without the axial movement of the collar along the axis and (b) a holder housing adapted to receive a sample collection tube within a rearward end.

In contrast, Hollister discloses a safety adapter, for use with a syringe (72) (See Fig. 4, reproduced below and Col. 6, line 63 to Col. 7 line 10).



In FIG. 4 of Hollister, a luer lock type syringe (72) has an internally threaded collar (76) surrounding male luer (74). Extension (18) at the distal end of section 2B is used to threadedly mate with thread (78) at the inner circumference of collar (76). Therefore any rotation of section 2B would result in an axial movement of collar (7) and shield (14) along the axis of the needle (68), as extension (18) follows thread 78.

Thus amended claim 1 and dependent claims 2 to 6 are not anticipated by the Hollister reference.

Furthermore the invention defined by amended claim 1 is neither taught nor rendered obvious by Hollister. Hollister has no suggestion of a safety shield and the collar are rotatable with respect to the holder housing about an axis of the holder housing, such that the safety shield and the collar can be radially rotated to a desired position around the axis without the axial movement of the collar along the axis. In fact, Hollister teaches away from a collar and shield that can be radially rotated around the axis without any axial movement of the collar along the axis as described above.

Accordingly, it is submitted that the holder assembly defined by amended claim 1 is not taught or suggested by Hollister.

(B) Claims 1-4, 27-33 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,298,541 to Newby et al. ("Newby").

This rejection is respectfully traversed with respect to the amendment to claim 1.

Of the claims rejected, claims 27-33 and 35 have been cancelled, amended claim 1 is independent, with the remaining claims dependent thereon.

Claim 1 now recites, among other things:

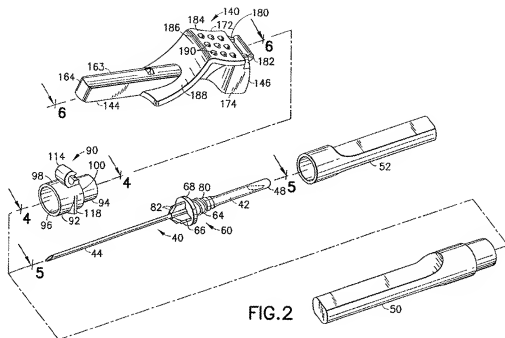
*a holder housing adapted to receive a sample collection tube within a rearward end, a forward end of the holder housing including;*

*a needle receiving port for receiving a needle cannula therein and*

*an annular skirt extending about the needle receiving port;.....*

*wherein the safety shield and the collar are rotatable with respect to the holder housing about an axis of the holder housing, such that the safety shield and the collar can be radially rotated to a desired position around the axis without the axial movement of the collar along the axis.*

Applicants submit that Newby fails to disclose at least the claimed features of: (a) the forward end of the housing holder including an annular skirt and (b) a safety shield and a collar that are rotatable with respect to the holder housing about an axis of the holder housing without the axial movement of the collar along the axis.



**FIG.2**

Applicants respectfully point out, that Newby discloses a collar (90) that has a forward annular skirt (92) and not the forward end of the housing holder (see Fig. 2 reproduced above, Col. 5 lines 16 to 18), furthermore hub (60) is joined with collar (90) by ultra-sonic welding techniques or any other bonding techniques (see Col. 6 lines 18 to 22). A needle holder is then screwed onto hub (60), therefore collar (90) and attached shield (140) cannot be rotated with respect to the holder housing without the axial movement of the collar along the axis.

Thus amended claim 1 and dependent claims 2 to 4 are not anticipated by the Newby reference.

**Claims Rejections – 35 USC § 103**

(C) Claims 7 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newby in view of U.S. Patent No. 5,197,954 to Cameron (“Cameron”).

This rejection is respectfully traversed in view of the amendments to claim 1 and original claim 23.

Of the claims rejected, claim 7 is dependent on amended claim 1, claim 23 is independent, with the remaining claims 24-26 dependent thereon.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant’s disclosure (see MPEP §2143).

The invention defined by amended claim 1 is neither taught nor rendered obvious by Newby.

Newby has no suggestion of the forward end of the housing holder including an annular skirt or a safety shield and a collar and a shield that are rotatable with respect to the holder housing without the axial movement of the collar along the axis.

In fact, Newby teaches away from the present invention for the following reasons:

- (a) the annular skirt (92) is an integral part of the collar (90) (and not the needle holder) that is bonded to the needle hub (60), and
- (b) any rotation of the safety shield and collar would result in the unscrewing removal of the hub from the needle holder, as the hub is bonded to the collar thus causing an axial movement of the collar along the axis.

Therefore Newby would have to be completely redesigned to be brought closer to the invention defined by amended claim 1. No such redesign is suggested. Accordingly, it is submitted that the holder assembly as defined by amended claim 1 is not taught or suggested by Newby.

Claim 23 is directed to a holder assembly comprising:  
*a holder housing adapted to receive a sample collection tube within a rearward end, a forward end of the holder housing including a needle receiving port for receiving a needle cannula therein, the holder housing having an annular skirt extending from the forward end, and a collar which attaches to the forward end of the holder housing, the collar having a hook arm for connection of a safety shield, wherein the annular skirt abuts the hook arm when the holder housing and the collar are in an attached position.*

Newby fails to disclose, teach, or suggest the claimed features of: (a) the holder housing having an annular skirt extending from the forward end and (b) a collar which attaches to the forward end of the holder housing.

As discussed above, Newby teaches a collar that is bonded to a hub which is attached to a needle holder.

In fact, Newby would have to be completely redesigned to be brought closer to the invention defined by claim 23. No such redesign is suggested. Accordingly, it is submitted that the holder assembly as defined by claim 23 is not taught or suggested by Newby.

Cameron teaches a hypodermic syringe having a folding needle, in which a needle hub (72) and hypodermic needle (28) are pivotably connected to a syringe barrel (12) and retained in position by an extension arm (84). Cameron does not overcome the deficiencies of Newby as explained above.

Therefore as claim 7 is dependent on claim 1, and claims 24-26 are dependent on claim 23, claims 7 and 23-26 are patentable over the cited references.

(D) Claims 8 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hollister in view of U.S. Patent No. 6,077,253 to Cosme.

This rejection is respectfully traversed in view of the amendment to claim 1.

Of the claims rejected, claim 8 is dependent on amended claim 1, and claim 21 has been cancelled.

Cosme was cited for teaching a holder assembly having a plurality of slits.

Cosme does not overcome the deficiencies of Hollister as set forth above in connection with amended claim 1, and being dependent on amended claim 1, claim 8 is patentable over the cited references.

**CONCLUSION**

In view of the amendments and remarks herein, applicants submit the claims are patentably distinct over the prior art and allowable in form.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication or credit any overpayment to Deposit Account No. 02-1666.

If the Examiner has any questions or comments relating to the present application, he or she is respectfully invited to contact applicants' agent at the telephone number set forth below.

Respectfully submitted,

/Mark Lindsey/

Mark Lindsey  
Registration No. 52,515  
Agent for Applicant(s)  
201 847 6262

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Becton, Dickinson and Company  
1 Becton Drive, MC110  
Franklin Lakes, New Jersey 07417-1880

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